Distribution Operations Center (DOC)

U.S. Army Medical Materiel Agency (USAMMA)

Cold Chain Management Briefing

Presented by

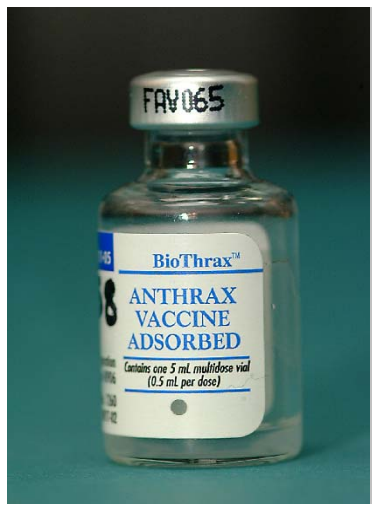
USAMMA/DOC

Agenda

- Mission
- Vision
- Principal Functions
- Cold Chain Management:
  - •Key Principles of Cold Chain Management/Distribution
  - •Temperature Sensitive Medical Products Management
  - •Equipment used to support Cold Chain Distribution
- Anthrax, Smallpox and Influenza Vaccines:
  - •Ordering Process
  - •Approval Process
  - •Inventories
  - •Disposition

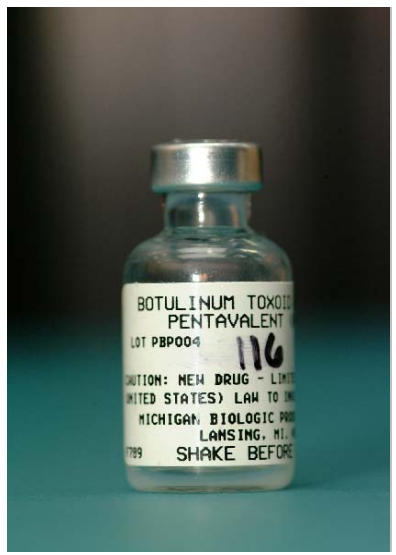
Mission

- We have the exclusive distribution management mission for the Department of Defense (DoD) of Anthrax and Smallpox vaccines to include other temperature sensitive medical Products (TSMPs). Additionally, we provide consultation and training on Cold Chain Management principles and procedures.



Vision

- To develop state of the art distribution mechanisms for temperature sensitive medical products in support of DoD objectives and to educate internal and external customers on the proper storage, receipt and distribution of these products.



Historical Perspective

- Inception and development of cold chain management principles created as a result of FREEZING loss of 200,000 doses of anthrax vaccine in 1998, ICE IS BAD

- 80% of vaccine/product loss and suspensions are due to FREEZING

- Comparison of military procedures with civilian; World Health Organization believes 50% of vaccine is temperature compromised

Principal Functions of USAMMA/DOC Personnel

- Accountability
- Ordering Procedures
- Education
- Visibility
- Order Fulfillment
- Escorts
- Real Time Tracking (Commercial Carriers)
- Prioritized Redistribution - Cross-leveling

What is Cold Chain Management?

- **Cold Chain Management is the process of preparing temperature sensitive medical products for shipment utilizing approved systems and procedures. This includes ensuring that required temperatures are maintained throughout the supply chain and validating that those conditions are met during all phases of distribution until issue or administration.**

Why Cold Chain Management is Important?

- **Assures Leadership, Service members and DoD beneficiaries that vaccine/product is safe to use and fully effective**

- **Minimize waste/Saves thousands of tax payers dollars**
  - Prevents vaccine from being compromised
  - Assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration
  - Some vaccines are in critically short supply

US Pharmacopoeia (USP) Temperature Standards

- **Refrigerated Storage -** Thermostatically controlled from 2°C to 8°C; approximately 36°F to 46°F

- **Frozen Storage** – Thermostatically controlled from -20°C to -10°C; approximately -4°F to 14°F

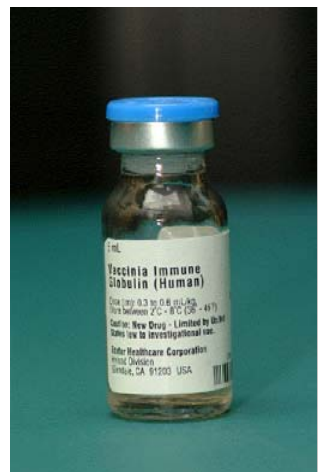
Key Principles of Cold Chain Management/Distribution

- Use of **Validated** Shipping **Containers** to keep products chilled at proper temperature, yet prevent **FREEZING**

- Inclusion of Temperature **Monitoring** Devices

- **Rapid Movement** of products - Partnership with Commercial Carrier Guarantees Express Delivery and asset visibility until delivery is completed

- I**nvolvement** with **knowledgeable** Customers



Safeguards that can be Implemented to Protect TSMPs

- Training
- Cooperation need with multiple disciplines
- Proper temperature monitoring
- Manual Checks and audible temperature alarm systems on a 24-hour basis
- SRP sites should have minimal stocks
- Alternate backup power for refers/freezers
- Proper labeling of refers/freezers
- Split stocks if possible
- Rotate stocks

Safeguards that can be Implemented to Protect TSMPs cont…

- **Standard Operating Procedures (SOP) must be developed with contact information for the following:**

  - Logistics, Pharmacy, Provost Marshal and Medical Maintenance personnel
  - Refrigerator repair technicians
  - Back-up storage areas
  - Temperature alarm repair technician
  - Dry Ice venders
  - Emergency repair companies
  - Vaccine Manufacturers

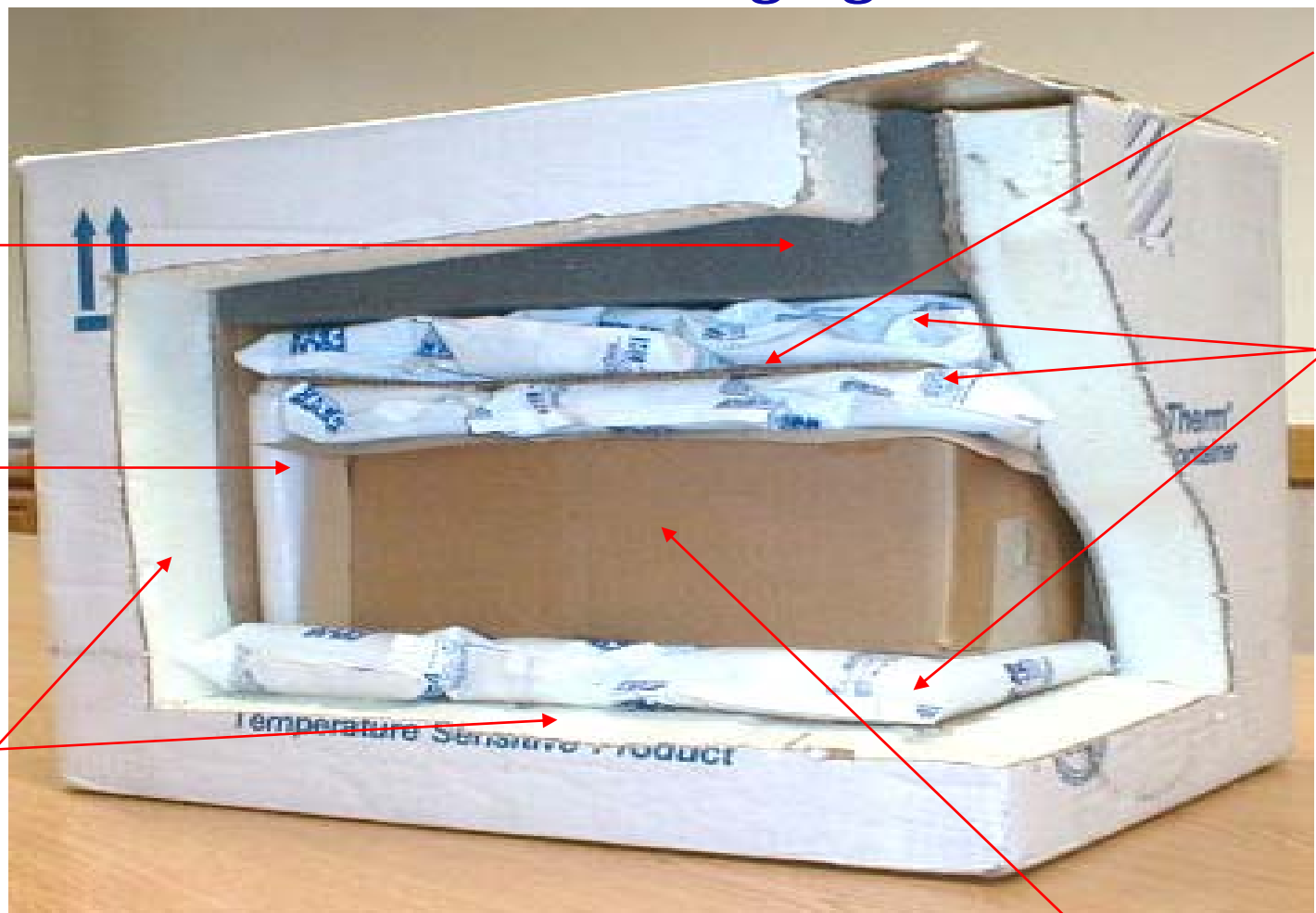
Equipment Used to Support CCM

- Validated shipping containers/boxes
- Temperature monitoring devices
- Gel packs (coolants/refrigerants)
- Packing Protocols
- Audible alarms

Endurotherm Boxes

Validated shipping containers and packing protocols assures product safety and efficacy

Endurotherm Insulated Shipping Containers Packaging



Fiberboard Barrier

Foam Plug

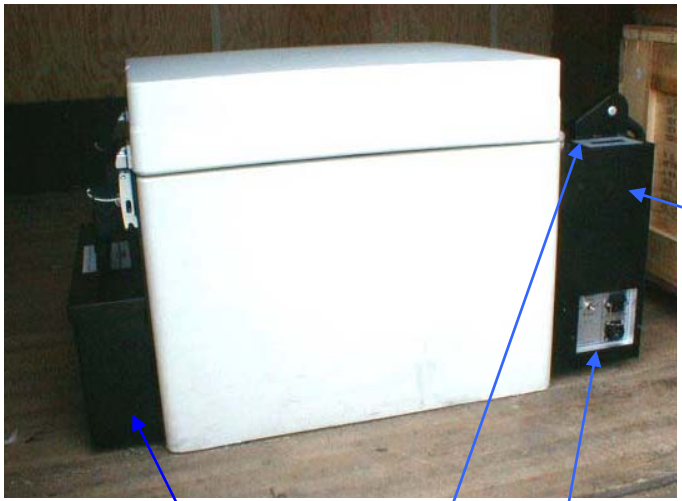
Gel Packs

Gel Packs Surrounding the Product

2” of Polyurethane Foam (Insulation)

Product and TempTale Temperature Monitor inside the fiberboard box

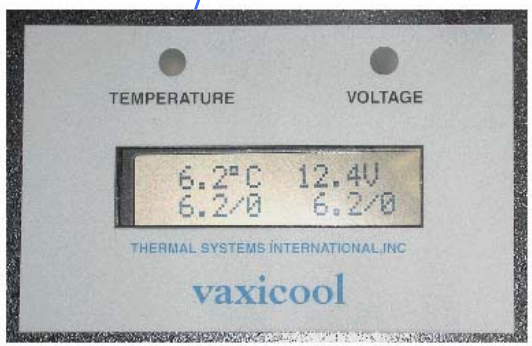
VaxiCool Dual Mode Container



THE SYSTEM IS COMPRISED OF:
a) A SUPER-EFFICIENT COMPRESSOR,
b) A SUPER INSULATED CONTAINER USING VACUPANEL INSULATION DESIGNED TO MAINTAIN VACCINES AT APPROPRIATE TEMPRATURE BETWEEN 2-8 CELSIUS.

BATTERY BOX CONTAINS
(2) 12 VOLT/20 AMPS
DRY GEL-CELL BATTERIES.

POWER PANEL CONTAINS SOLAR INPUT PLUG, AC POWER FROM 90-270 VOLTS.

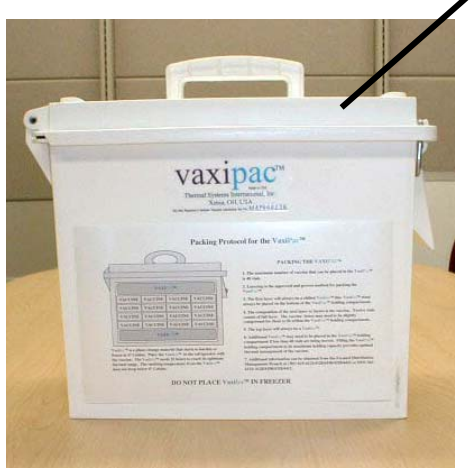


LCD SCREEN DISPLAYS THE TEMPERATURE AND BATTERY VOLTAGE.

VAXICOOL HAS AN INSIDE DIMENSION OF 14 (LENGTH) BY 10-1/2 (WIDTH) BY 10 (DEPTH) ITS PAYLOAD

VaxiPac Shipping Container

VaxiPac is used for transport of small quantities of refrigerated products



EXTERIOR DIMENSION OF 15 (LENGTH) BY 7.75 (WIDTH) BY 11.38 (DEPTH)

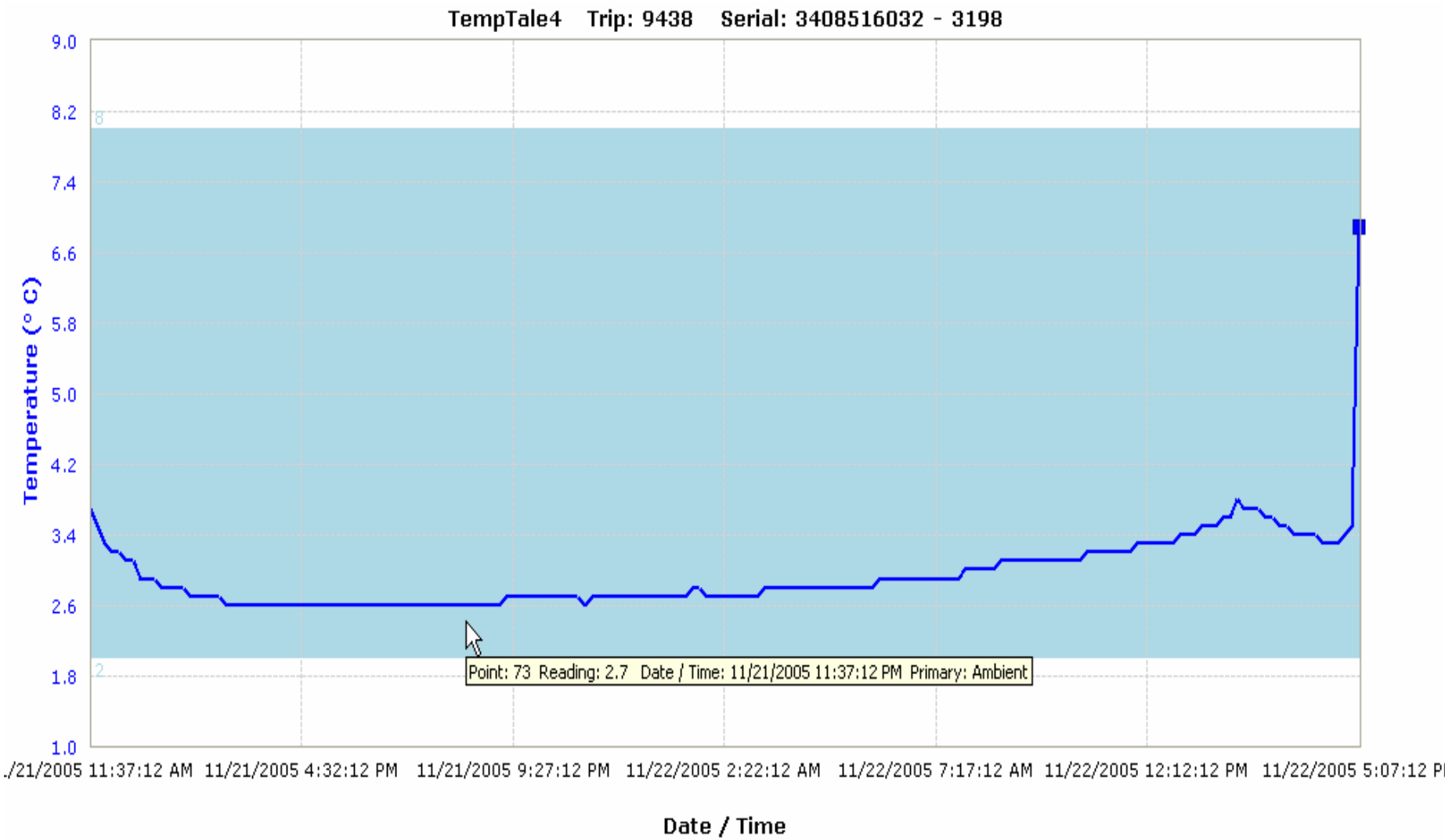
WALLS LINED WITH VACUPANEL INSULATION

VAXISAFE IS A PHASE CHANGE MATERIEL (PCM) THAT STARTS TO HARDEN OR FREEZE AT 6 CELSIUS.

Temperature Monitors

Primary Operating Range	-22ºF to +158ºF (-30ºC to +70ºC)
Primary Sensor Options	Ambient Temperature only
Primary Sensor Accuracy	±2ºF from -22ºF to 0ºF (±1ºC ºFrom -30ºC to -18ºC) ±1ºF from 0ºF to +122ºF (±0.5ºC from -18ºC to +50ºC) ±2ºF from +122ºF to +158ºF (±1ºC from +50ºC to +70ºC)
Memory Size	1,920 Data Points
Temperature Alarms	LCD Alarm for single event or cumulative time out of range
Start-Up Delay	Minimum - 0 Seconds Maximum - 194 Days
Measurement Interval	Minimum - 10 Seconds Maximum - 2 Hours
Primary Sensor Resolution	0.1º (1/10º)

TempTale Download Data



Packing Protocols

The following packing protocols were developed to ensure maximum protection for temperature sensitive medical products requiring storage temperatures between 2°C and 8°C (36°F and 46°F) during distribution:

Cold weather: Is used when ambient temperature at the receiving site consistently remains below 55°F. All gel packs used are refrigerated or chilled to +4°C.

Moderate weather: Is used when ambient temperature at the receiving site is between 55°F and 77°F. Uses a combination of chilled and frozen gel packs.

Warm weather: Is used when ambient temperature at the receiving site is consistently above 77°F. Uses a combination of chilled and frozen gel packs.

NOTE: Packing protocols are designed to hold 2°C to 8°C for at least 72 hours or longer.

Temperature Recorders with Remote Monitoring and Audible Alarms

Anthrax and Smallpox Vaccines Ordering Process

- **Customers must register on line (USAMMA/DOC secured website) and create own log-in and password:**
  - DOC personnel and local Service POCs validate registration
  - DOC personnel enables customer in our DOC's secure server
  - Customer receives authorization to access our secure webpage via email

Approval Process

Army:

Sandra Rogers - Validate
MAJ Doulaveris - Approving Officer

Navy/Marines: - NAVMEDLOGCOM

HMC Scruggs - Validate (Navy and Marines)
Mrs. Louise McLucas - Validate (Navy and Marines)
LCDR Donohue - Approving Officer (Navy)
HQMC - HMC Palmares / Mr. Frank Lepe - Approving Official (Marines)

Air Force: - AFMSA

Jan Mitchell - Validate
MAJ Cindy Thomas - Approving Officer (Active Duty)
MSgt Michelle Miller - Approving Officer (ANG)
Pat Tooley - Approving Officer (Air Reserves)

Coast Guard:

CDR Monica Kueny – Validation and Approving Officer

Vaccine Inventory

- **DoD activities are required for reporting a monthly inventory of the anthrax and smallpox vaccine (Reference DOD-MMQC-04-1143)**

- **Inventory Requirements:**
  - Logistics Activities and customers are required to report their physical inventories by the first Friday of each month to their major commands
  - Major Commands are required to report their physical inventories by the second Friday of each month to USAMMA/DOC
  - **Vaccine Reports must include:**
    - Number of unopened vials and kits by lot number

I suspect the vaccine is compromised What do I do?

- **I will:**
  - Contact USAMMA – Do not contact the Manufacturer
  - Prepare Executive Summary (EXSUM)
  - Destroy the vaccine if necessary (After consulting USAMMA)

- **Causes that may compromise your vaccine:**
  - Power Failure
  - Refer/freezer malfunctions
  - Vaccine sitting out of the refrigerator for extended period of time/improper storage of vaccine
  - Shipping mis-sort/frustrated cargo

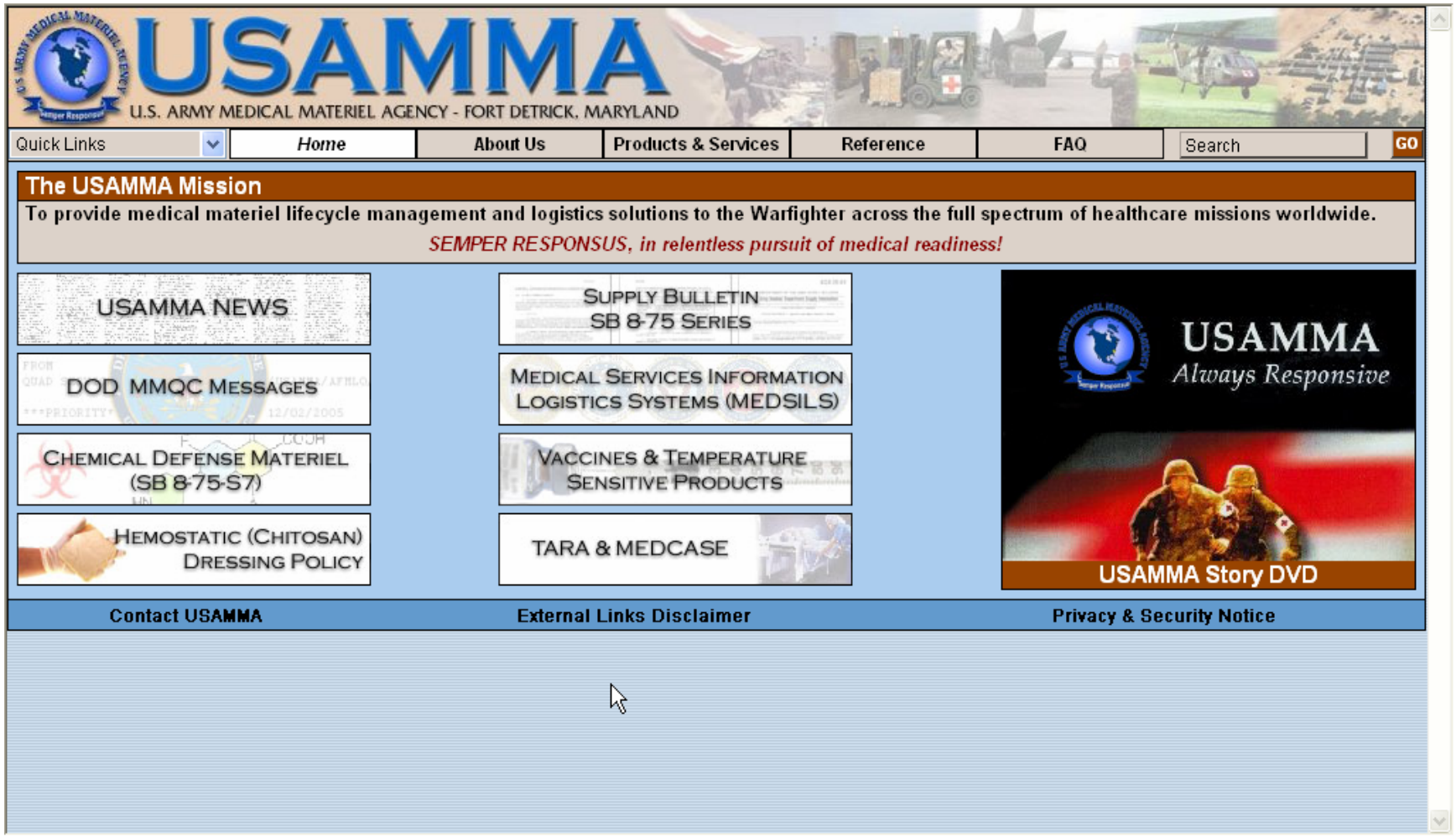
Executive Summary (EXSUM)

- DoD Activities are responsible for reporting any loss of Anthrax, Smallpox and Flu Vaccine, due to expiration, or loss of efficacy by another means
- EXSUM submitted in Memorandum Format
- EXSUM should be routed up the chain of command for review and endorsement before faxing/emailing to USAMMA/DOC
- USAMMA/DOC must receive the EXSUM from activities before replacement of vaccine will be shipped

Vaccine Disposal

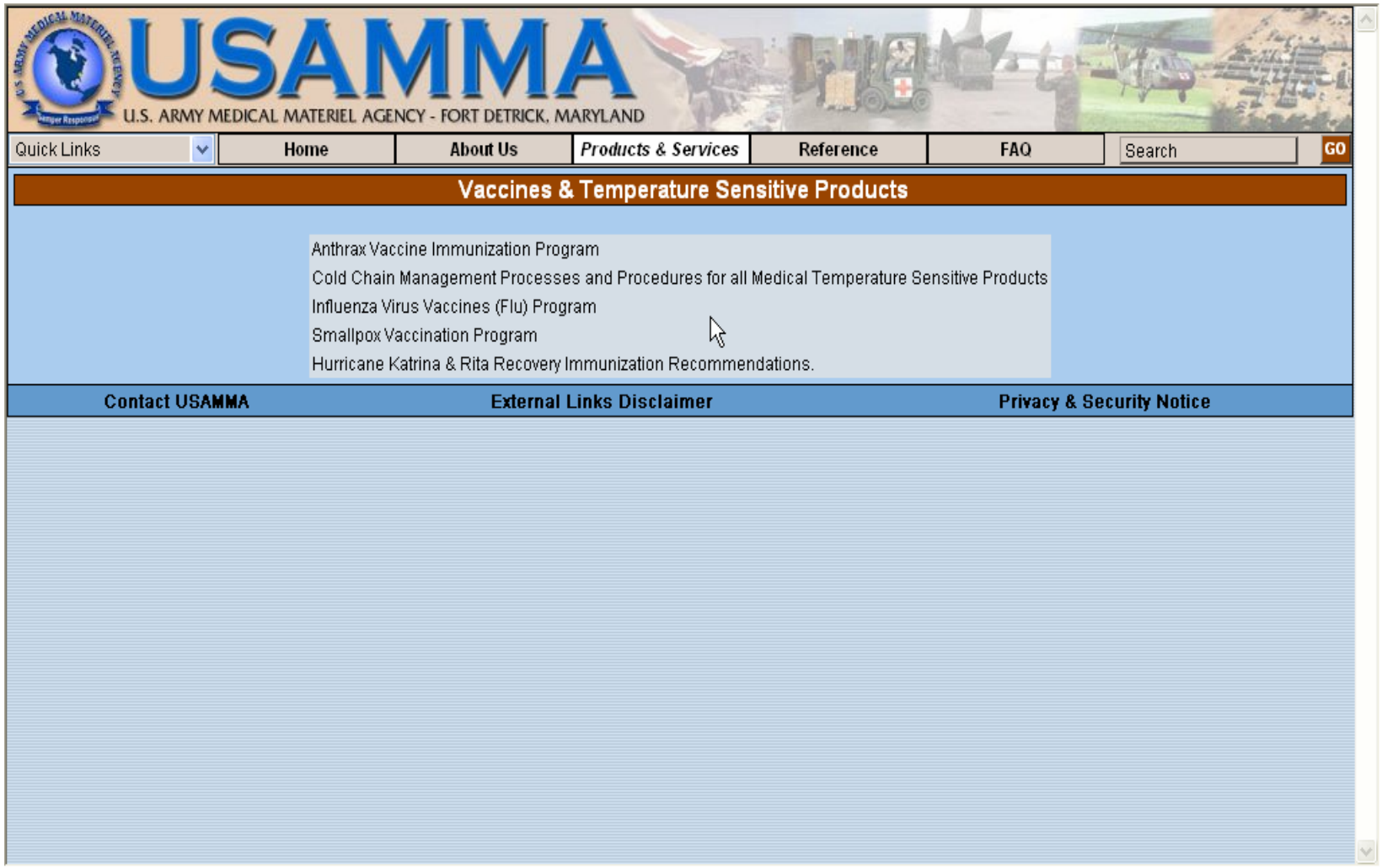
- DoD activities are responsible for disposal of compromised or expired vaccine
- Destruction memorandum should be routed up the chain of command for review and endorsement before faxing to USAMMA/DOC
- Methods of destruction:
  - AVA/FluZone/FLUMIST: can be disposed in sharps container, autoclaved, incinerated, or use a returns program
  - Smallpox: DO NOT DISPOSE OF SMA VACCINE (DRYVAX) UNLESS DIRECTED VIA A MEDICAL MATERIEL QUALITY CONTROL MESSAGE (MMQC)
    - Vaccine vials can be dropped into the hospital sharps container, autoclaved, or disposed of following the procedure for all other biohazard materials
- AVA, SMA and Flu disposition instructions available at:
  http://www.usamma.army.mil/vaccines/anthrax/antxhome.htm
  Destruction Codes can be found on the USACHPPM website:
  http://chppm-www.apgea.army.mil

USAMMA Website



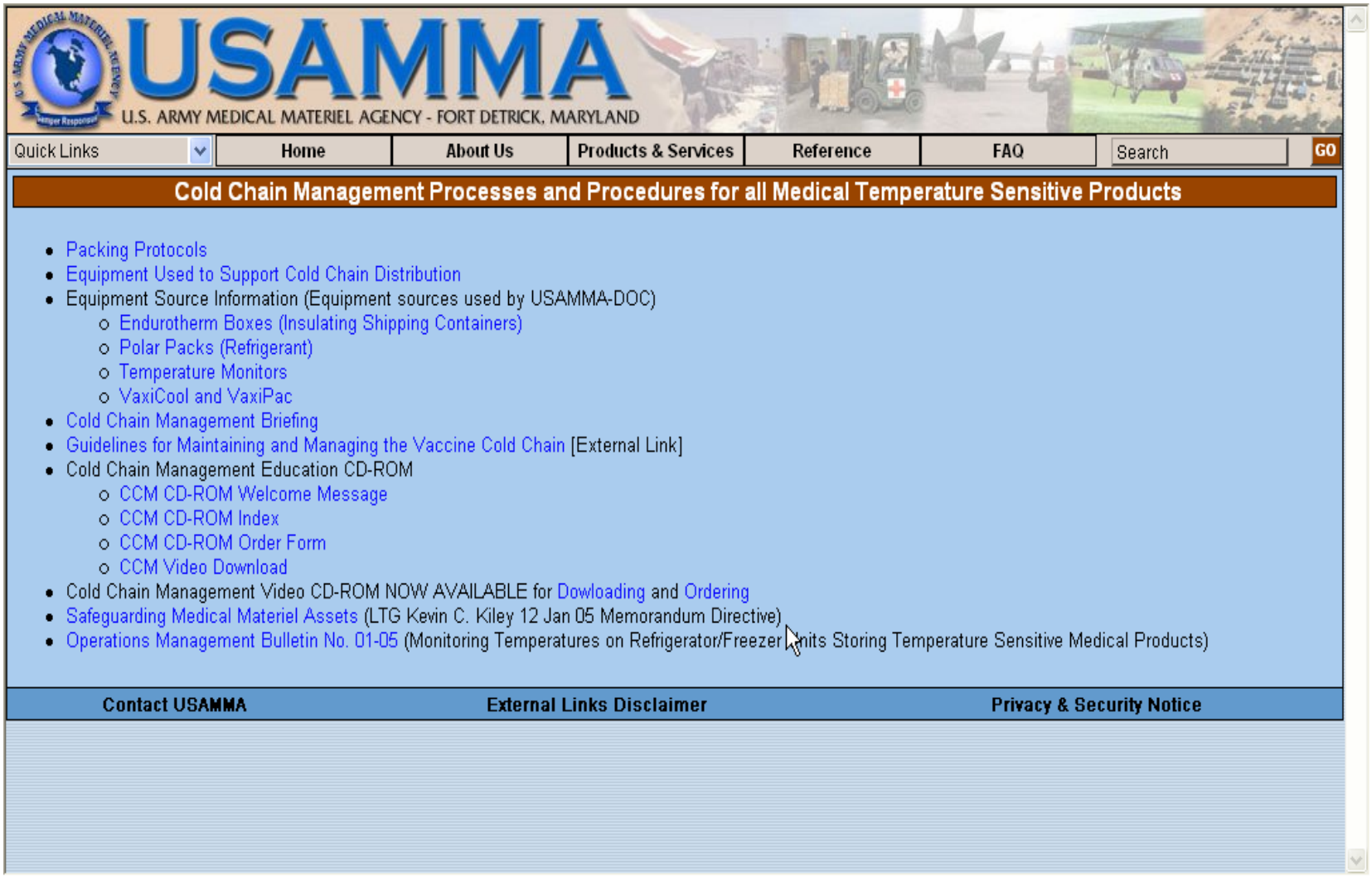
www.usamma.army.mil

Distribution Operations Center Links



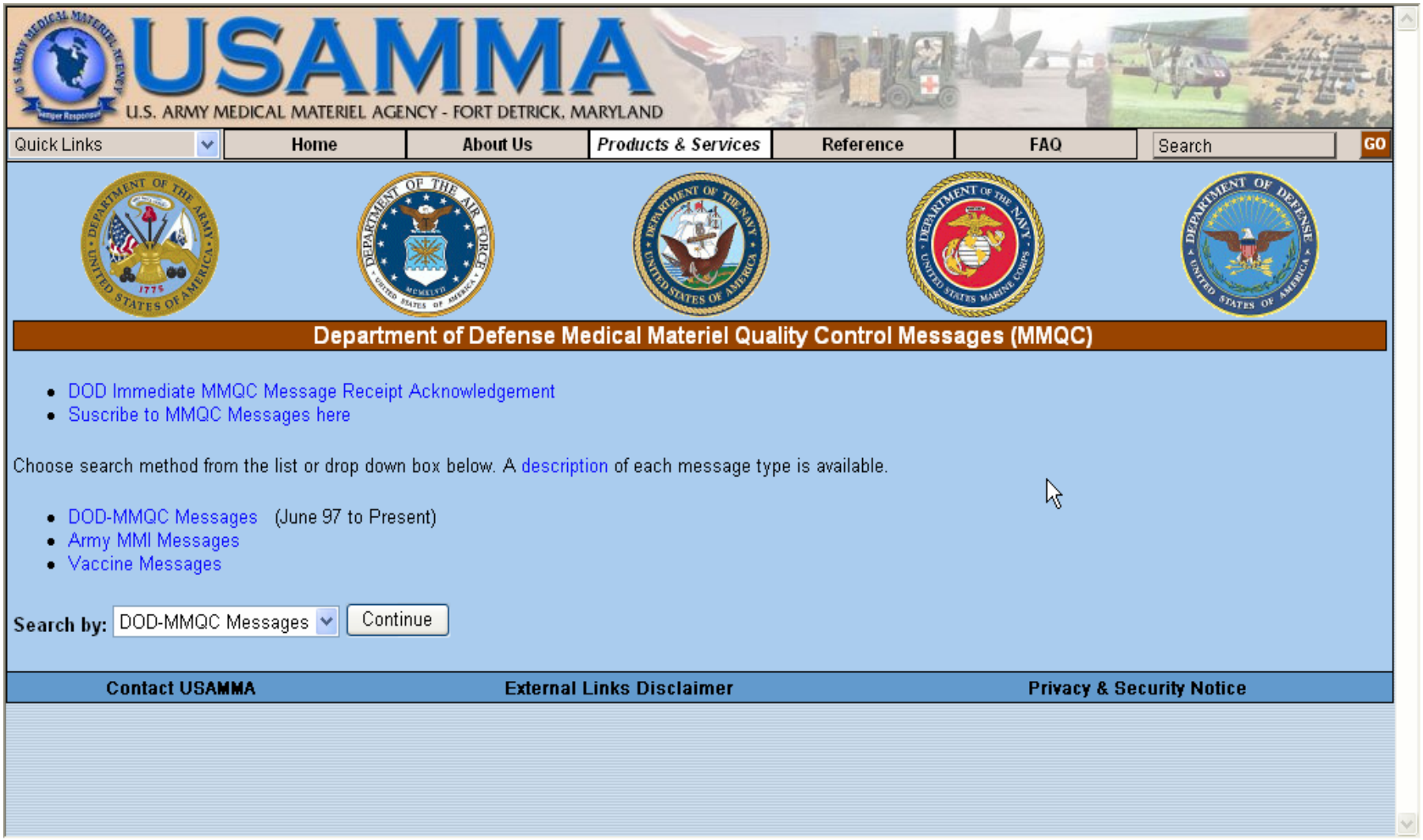
http://www.usamma.army.mil/vaccines/vaccines.cfm

Cold Chain Management Links



http://www.usamma.army.mil/vaccines/CCM/Cold_chain_mangement.cfm

MMQC Messages Registration Site



http://www.usamma.army.mil/apps/nala_qaweb/nala_index.cfm